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IN THE UNITED STATES DISTRICT COURT
THE DISTRICT OF NEW JERSEY

ASTRAZENECA AB, AKTIEBOLAGET HÄSSLE, ASTRAZENECA LP, KBI INC., and KBI-E INC., Plaintiffs and Counterclaim Defendants, v. HANMI USA, INC., HANMI PHARMACEUTICAL CO., LTD., HANMI FINE CHEMICAL CO., LTD, and HANMI HOLDINGS CO., LTD., Defendants and Counterclaim Plaintiffs.	Civil Action No. 11-760 (JAP)(TJB)

Hanmi's Motion in Limine No. 4
(To Preclude AstraZeneca From Attempting To Introduce Evidence Alleging Invalidity or Unenforceability of Hanmi's Patents)

Hanmi hereby moves *in limine* to preclude AstraZeneca from introducing evidence or argument alleging invalidity or unenforceability of *Hanmi's* patents relating to its esomeprazole strontium tetrahydrate product.

A. Context of Relevance of Hanmi's Patents

Whether AstraZeneca can prove infringement by Hanmi's proposed product or its use under the doctrine of equivalents will be a core issue at trial. It is undisputed that Hanmi's product, which is a strontium salt, is outside the literal scope of the asserted claims based on the Court's *Markman* rulings on "alkaline salt" ('504 patent) and "pharmaceutically acceptable salt" ('192 patent). D.I. 257, Opinion dated December 2012, pp. 5-8 and 11-14.

Proof of infringement under the doctrine of equivalents requires the patentee to show that there be an insubstantial difference between the limitations of the claim and the accused product, on an element-by-element basis. *See Warner-Jenkinson Co. v. Hilton Davis Chem. Co.,* 520 U.S. 17, 29, 39-41 (1997). Factors to be considered in assessing the substantiality of the differences include: (1) whether persons skilled in the art would have known of the interchangeability of an ingredient not contained in the patent with one that was; (2) evidence of copying; (3) efforts to design around the claims of a patent; and (4) evidence of independent development. *Id.* at 29, 39-41.

In support of its position that substantial differences exist, Hanmi intends to introduce its own patents covering its strontium salt product (U.S. Patents 8,106,076 (Ex. 29) and 7,576,219 (D.I. 111-10)) as well as the process used to manufacture the active ingredient (U.S. Patent 7,888,511 (Ex. 30)). *See* D.I. 220, May 24, 2012 letter, M. Tarantino to Judge Pisano regarding Hanmi patents; *see, e.g.*, Ex. 17, Second Expert Report of Wayne J. Genck, section II at pp. 39-48; Ex. 18, Second Expert Report of Jerry L. Atwood, pp. 30-37. As explained therein, Hanmi's

'076 product patent was obtained directly over the two AstraZeneca patents-in-suit, while both the '076 and '219 patents refer to the '504 patent in the background section.

Hanmi's separate patenting of its strontium salt is highly relevant evidence on the "substantial differences" factors set forth in *Warner-Jenkinson*. Although separate patenting is not dispositive of substantial differences, it is relevant and entitled to due weight. *Zygo Corp. v. Wyko Corp.*, 79 F.3d 1563, 1570 (Fed. Cir. 1996). In *Festo Corp. v. Shoketsu Kinzoku Kogyo Kabushiki Co.*, the Federal Circuit stated,

> [W]hen a device that incorporates the purported equivalent is in fact the subject of a separate patent, a finding of equivalency, while perhaps not necessarily legally foreclosed, is at least considerably more difficult to make out. But there is a strong argument that an equivalent cannot be both unobvious and insubstantial."

493 F.3d 1368, 1379-80 (Fed. Cir. 2007) (internal footnotes omitted).[1]

B. AstraZeneca's Improper Deposition Tactics Should Be Barred At Trial

The evidence at trial will establish Hanmi's patenting of its strontium salt directly over the two AstraZeneca patents-in-suit. Those facts cannot be disputed. Because AstraZeneca cannot dispute that at least the '076 Hanmi patent covers the accused product and was expressly granted over the '504 and '192 patents-in-suit, AstraZeneca resorts to slinging mud at Hanmi and its patents. AstraZeneca should be prevented from seeking to introduce evidence alleging "invalidity" or "unenforceability" of Hanmi's patents relating to its esomeprazole strontium tetrahydrate product.

[1] *See also* the concurring opinion in *Roton Barrier, Inc. v. Stanley Works*, in which Judge Nies wrote that "a second patent, depending on its subject matter, may be relevant to the issue of whether the changes [in an accused device] are substantial," and that "[a] substitution in a patented invention cannot be both nonobvious and insubstantial." 79 F.3d 1112, 1128 (Fed. Cir. 1996) (Nies, J., additional views).

In more than one deposition, counsel for AstraZeneca has insisted on lines of questioning of Hanmi's fact and expert witnesses, asserting that Hanmi's '219 patent is "invalid," or is unenforceable due to "inequitable conduct." *See* Ex. 19, Selected Excerpts from the September 29, 2012 Deposition Transcript of Kwee Hyun Suh, at pp. 251-290 (questions suggesting that one statement in Hanmi's '219 patent relating to optical purity was incorrect and that Hanmi allegedly concealed information from the Patent Office, despite testimony that the statement is correct in context); Ex. 20, Selected Excerpts from the April 25, 2013 Deposition Transcript of Wayne Genck, at pp. 199-203 (asking him to "assume" that Hanmi's '219 patent is invalid and unenforceable for inequitable conduct, and how that would affect his views). Besides being baseless, any such speculation is irrelevant to any issue in the case. The Patent Office's decision to grant the Hanmi patents over the AstraZeneca patents-in-suit is what is relevant to the issue of whether the differences are substantial ones. Hanmi's patents are presumed to be valid, 35 U.S.C. § 282, and speculative questioning of Hanmi's witnesses on some ill-defined, unsupported and unproven theory of "invalidity" should be barred.

Allegations of "inequitable conduct" are serious charges, and AstraZeneca should be precluded from making any such unsupported allegations at trial, particularly in light of the Federal Circuit's extremely high standards for showing materiality and intent to deceive. *See, e.g.*, *1st Media v. Electronic Arts,* 694 F.3d 1367, 1374-75 (Fed. Cir. 2012) ("[K]nowledge of the reference and knowledge of materiality alone are insufficient after *Therasense* to show an intent to deceive. Moreover, it is not enough to argue carelessness, lack of attention, poor docketing or cross-referencing, or anything else that might be considered negligent or even grossly negligent. To sustain a charge of inequitable conduct, "clear and convincing evidence must show that the applicant made a deliberate decision to withhold a known material reference."); *see also Exergen*

Corp. v. Wal-Mart Stores Inc. and S.A.A.T. Systems, 575 F.3d 1312, 1329 (Fed. Cir. 2009) (a pleading of inequitable conduct under Rule 9(b) must include ***sufficient allegations*** of underlying facts from which a court may reasonably infer that a specific individual (1) knew of the withheld material information or of the falsity of the material misrepresentation, and (2) withheld or misrepresented this information with a specific intent to deceive the PTO).

AstraZeneca apparently wishes to engage in a "smear campaign" against Hanmi at trial – a trial which will already be complicated enough based on issues properly in the case. The validity and enforecability of Hanmi's patents are not issues for trial in this case. Furthermore, AstraZeneca has proffered no expert testimony on its irrelevant theories nor presented any bases in its contentions. It is well-established that the scope of an expert's opinions at the trial is limited to the opinions disclosed in that expert's report. *See, e.g.*, *O2 Micro Int'l, Ltd. v. Monolithic Power Sys., Inc.*, 467 F.3d 1355, 1368-69 (Fed. Cir. 2006) (affirming district court's exclusion of expert opinions concerning matters not disclosed in the opening expert reports). *See also Northlake Mktg & Supply, Inc. v. Glaverbel, S.A.*, No. 92 C 2732, 1996 U.S. Dist. LEXIS 19306, at *5-6, *11 (N.D. Ill. Dec. 17, 1996) (granting motion *in limine* to exclude expert from testifying on matters not set out in his initial report). Thus, AstraZeneca has no basis upon which to found any argument or examination of witnesses concerning the validity and enforceability of Hanmi's patents.

For all of these reasons, any argument or evidence at trial, including attempted examination of Hanmi witnesses at trial who will testify about Hanmi's patents, should not be permitted with respect to any AstraZeneca unsupported allegations of invalidity or unenforceability, which simply are not issues properly in the case in any event.

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CERTIFICATE OF SERVICE

I hereby certify that on April 29, 2013, I caused a copy of the foregoing **Hanmi's Motion in Limine No. 4 (To Preclude AstraZeneca From Attempting To Introduce Evidence Alleging Invalidity or Unenforceability of Hanmi's Patents)** to be served upon the following counsel by electronic mail:

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